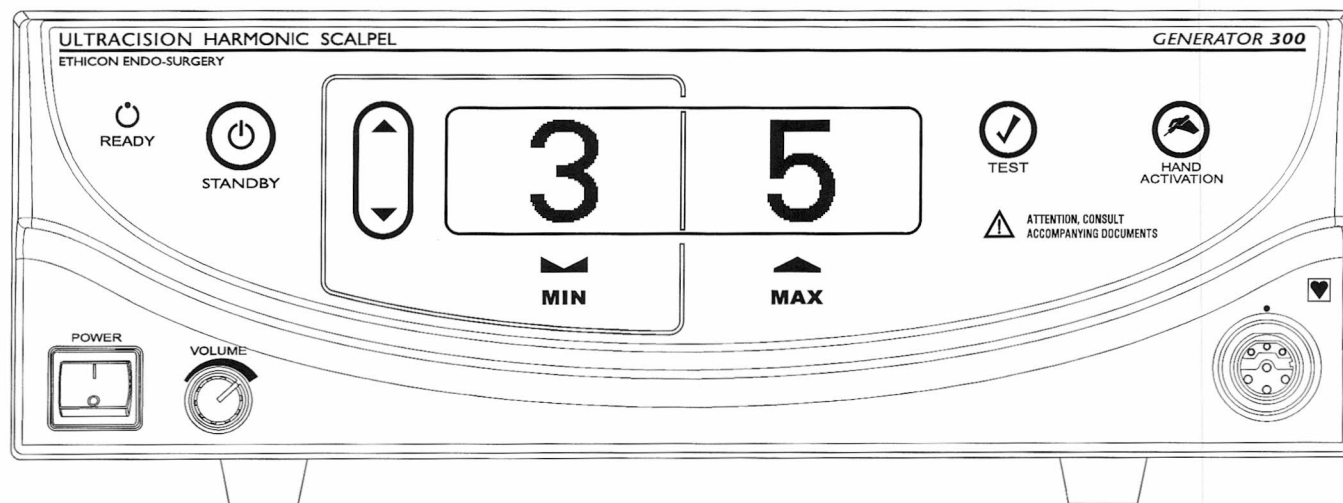


ULTRACISION® HARMONIC SCALPEL®

Generator 300 System Service Manual



Components Needed

- 1 ULTRACISION HARMONIC SCALPEL Hand Piece (HP054/HP055)
- 1 ULTRACISION HARMONIC SCALPEL Hand Piece Test Tip (HST02)
- 1 ULTRACISION HARMONIC SCALPEL Foot Switch (FSW01) or Hand Switching Adaptor (HSA07)
- Torque Blade Wrench (TLB01)

Equipment Needed

- DMM (Digital Multi-Meter) with the following specifications:
 - True RMS Voltage Measurements
 - 300 kHz Minimum Bandwidth
 - 4 Digits Minimum Resolution
 - ACRMS Tolerance
- Screwdriver

Required Schedule

Calibration is **required** on the ULTRACISION HARMONIC SCALPEL Generator 300 every **twelve months**.

Proof of calibration should be documented according to hospital procedures.

Generators can be returned to Ethicon Endo-Surgery, Inc. for calibration, but this is not covered in the warranty. A minimal charge will be assessed. This can be done by calling 1-800-USE-ENDO (U.S. Customers). International Customers should contact their Ethicon Endo-Surgery, Inc. representative for assistance.

Calibration Procedures

Complete the following Calibration procedures every 12 months according to hospital procedures.

Caution: Use proper hospital safety procedures when performing a calibration.

Calibration One

The Calibration One procedure is used to enter/input the Level 3 current read by an external, calibrated meter.

Step		Result
1	Unplug all connections to the generator. Remove the generator cover by removing the casing screws and sliding the cover towards the back of the unit.	<input type="checkbox"/>
2	Connect hand piece and foot switch (or hand switching adaptor) to their respective connections on the uncovered generator. Attach a test tip to the hand piece, and torque on using a torque blade wrench.	<input type="checkbox"/>
3	Connect a power cord to the uncovered generator. Use caution when working around generator components while the generator is powered ON.	<input type="checkbox"/>
4	Enter Developer/BME mode by simultaneously holding the STANDBY button and DOWN arrow button on the generator while powering ON. The Developer/BME mode screen will be displayed. The buttons can be released when the indicator icons light up.	<input type="checkbox"/>
5	Scroll to Page 2, using the UP and DOWN arrow buttons. Record the 'Current Setpoint' value.	____mA
6	75% of the value recorded in Step 5 is the Level 3 current. Calculate and record this value by multiplying the Step 5 value above by 0.75 .	____mA
7	Press the STANDBY button to enter READY state.	<input type="checkbox"/>
8	Set the MIN level to Level 3 (this is the default level).	<input type="checkbox"/>
9	Activate the hand piece at Level 3 by pressing the MIN foot switch pedal, or activating the MIN hand switching adaptor button. Ensure the test tip is activating in air and is not in contact with anything. Allow the Pre-Run tests to complete.	<input type="checkbox"/>
10	While continuing to press the MIN Level 3 foot switch pedal or MIN hand switching adaptor button, measure the RMS voltage across both current-sense resistors on the main board, R233 and R234 (which are in series). To measure using probes, place the positive and negative probes on the outside of each of the resistors R233 and R234, respectively. To measure using alligator clips, clip to the post of R229 closest to R233, and to the post of C177 closest to R234. Either of these connection schemes (probes or clips) will measure the voltage across R234 and R233 as required. Note: This measurement MUST be taken with a Digital Multi-Meter (DMM) consistent with the specifications listed in the Equipment Needed section of this manual. Using a DMM that does not meet these specifications will cause errors in the calibration procedure.	<input type="checkbox"/>
11	Record the DMM voltage from Step 10, to four digits of precision. The two resistors in series are a total of 1 ohm, so the value measured in volts is equivalent to the current in amperes. ($V=IR$) Record this equivalent current.	____mA
12	Deactivate the hand piece by releasing the foot switch or hand switch MIN or MAX button.	<input type="checkbox"/>

- 13 While in Developer/BME mode, press STANDBY to enter the Standby state. ☐
- 14 Scroll to Page 17 by using the UP and DOWN arrow buttons. ☐
- 15 Adjust the VOLUME knob to obtain the Level 3 current recorded in Step 11. Press the TEST button when this value is displayed on the screen. ☐
- 16 The text 'Value Accepted!' should flash twice if the calibration was successful. ☐
- 17 Power OFF the generator for a few seconds. Power ON the generator and enter Developer/BME mode by simultaneously holding down the STANDBY button and the DOWN arrow button on the generator while powering ON. The buttons can be released when the indicator icons light up. ☐
- 18 Press the STANDBY button to enter the Ready state. ☐
- 19 Activate the hand piece using the MIN foot switch pedal or MIN hand switching adaptor button at Level 3. Allow the Pre-Run tests to complete. ☐
- 20 While continuing to press the MIN Level 3 footswitch pedal or MIN hand switching adaptor button, again, measure the VAC RMS output voltage simultaneously across **both** of the current-sense resistors, R233 and R234, as in Step 10 above. ☐
- 21 Verify the current in Step 20 is within 1% of the Step 6 calculated value. mA
- 22 Power OFF the generator and continue to the Calibration Two procedure. ☐

Serial Number _____

Results _____ Pass _____ Fail

Software Version _____

Completed By _____

Date _____

Calibration Two

The Calibration Two procedure is used to confirm the output read by the generator is correct and to enter this confirmation. This procedure is performed without an external meter. The Calibration One procedure must be performed prior to the Calibration Two procedure.

Step		Result
1	Connect hand piece and foot switch (or hand switching adaptor) to their respective connections on the generator. Attach a test tip to the hand piece, and torque on using a torque blade wrench.	<input type="checkbox"/>
2	Enter Developer/BME mode by simultaneously holding the STANDBY button and DOWN arrow button on the generator while powering up. The Developer/BME mode screen will be displayed. The buttons can be released when the indicator icons light.	<input type="checkbox"/>
3	Scroll up to Page 2, using the UP and DOWN arrow buttons. Record the 'Current Setpoint' value.	____mA
4	75% of the value recorded in Step 3 is the anticipated Level 3 current. Calculate and record this value by multiplying the Step 3 value above by 0.75.	____mA
5	Go to Ready mode and activate the generator at Level 3 for more than one second after the pre-run test is completed, using the MIN foot switch or hand switching adaptor button. Ensure the test tip is activating in air and is not in contact with anything.	<input type="checkbox"/>
6	Deactivate the hand piece by releasing the foot switch or hand switching adaptor buttons.	<input type="checkbox"/>
7	While in Developer/BME mode, press the STANDBY button.	<input type="checkbox"/>
8	Scroll to Page 18 using the UP or DOWN arrow buttons.	<input type="checkbox"/>
9	Press the TEST button to accept the Level 3 calibration current value. Record the current displayed on the screen.	____mA
10	The text 'Value Accepted!' should flash twice if the calibration procedure was successful.	<input type="checkbox"/>
11	Power OFF the generator. Enter Developer/BME mode by simultaneously holding down the STANDBY button and the DOWN arrow button while powering ON generator.	<input type="checkbox"/>
12	Press the STANDBY button to enter the Ready state.	<input type="checkbox"/>
13	Activate the hand piece at Level 3 by pressing the MIN foot switch pedal, or activating the MIN hand switching adaptor button for more than one second. Ensure The test tip is activating in air and not in contact with anything. Press the STANDBY button to enter the Standby state.	<input type="checkbox"/>
14	Record the current displayed on Page 18.	____mA
15	Verify that the reading in Step 13 is within 1% of the the value from Step 4. If not, carefully re-execute both the Calibration One and Calibration Two test procedures again.	<input type="checkbox"/>

Serial Number _____

Results _____ Pass _____ Fail

Software Version _____

Completed By _____

Date _____